

FIRST AMENDMENT AND RESPONSE TO OFFICE ACTION

U.S. Serial No.: 10/712,419

Filed: November 12, 2003

Page 5 of 9

REMARKS

The present application is directed to methods, devices, and kits for the detection and concentration or purification of an analyte. In particular, the application relates to the concentration of an analyte using an assay such as an immunoassay to facilitate confirmation of a positive assay result.

Claims 1-13 are pending. Claims 1 and 5-10 are currently amended, and new Claims 11-13 are added. Favorable consideration of the currently pending claims is respectfully requested in light of these amendments and the following remarks.

Claim rejections under 35 U.S.C. §102(b)

In the Office Action mailed July 27, 2004, the Examiner rejected Claims 9 and 10 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,900,379 to Noda *et al.* on the basis that Noda *et al.* disclose a test kit with a lateral flow device having a section that is removable. The Examiner further states that the removable section contains a capture region where immobilized antibodies are used to capture an analyte. Applicants respectfully traverse the rejection.

Noda *et al.* teach that “the cassette is in the form of a strip having two ends and includes a **first absorbent material, a membrane immunoassay and an optional second absorbent material** and a cassette support means” (see column 3, lines 29-32, emphasis added). Noda *et al.* further teach that the first absorbent material, the second absorbent material, or both may be removed from the cassette (see column 4, lines 9-11 and claim 15). The first absorbent material and second absorbent material fail to contain bound analyte material. The bound analyte is retained in the membrane immunoassay portion of the cassette. Applicants respectfully submit that Noda *et al.* fail to teach the removal of the **membrane immunoassay** (the portion containing the bound analyte) from the cassette.

The claims of the present application have been amended to clarify that the portion of the device **containing the bound analyte** is separated from at least part of the device, and the portion of the device **containing the bound analyte** is analyzed to provide information

FIRST AMENDMENT AND RESPONSE TO OFFICE ACTION

U.S. Serial No.: 10/712,419

Filed: November 12, 2003

Page 6 of 9

regarding the suspected analyte. Support for this amendment can be found on at least page 15, lines 11-16.

Applicants submit that Noda *et al.* fail to teach removal and analysis of the portion of the device **containing the bound analyte** as claimed in the present application. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §102(b).

In the Office Action mailed July 27, 2004, the Examiner rejected Claims 1-6 under 35 U.S.C. §102(b) as being anticipated by Mazar *et al.* (U.S. Patent No. 6,277,818). The Examiner states that Mazar *et al.* disclose a method for isolating or enriching uPAR-expressing cells from a cell mixture by contacting the cell mixture with a binding compound that is bound to a solid support such as a resin, flat sheet, test strip, etc. and **separating cells from the ligand**, thereby enriching or isolating the cells. The Examiner further states that Mazar *et al.* also disclose further enriching the cells by plating and growing them in an appropriate medium. Applicants respectfully traverse the rejection.

The claims of the present application reflect that the “portion containing the bound analyte” is formed as a result of the analyte binding to the immobilized binding partner. The portion containing the bound analyte is then separated from the device. The separated portion “containing the bound analyte” will, by default, also contain immobilized binding partner. The separated portion (containing both the bound analyte and immobilized binding partner) is then further analyzed to provide information regarding the suspected analyte, without detachment from the immobilized binding partner.

In contrast, Mazar *et al.* teach a method for isolating or enriching uPAR-expressing cells from a cell mixture by contacting the cell mixture with the uPAR-binding ligand compound (cyclic peptide); allowing any uPAR expressing cells to bind to the compound (that is bound to a solid support such as a resin, flat sheet, test strip, etc); separating cells bound to the ligand from unbound cells (e.g. lateral flow movement of sample through test-strip); and **removing the bound cells from the ligand**, thereby isolating or enriching the uPAR expressing cells.

FIRST AMENDMENT AND RESPONSE TO OFFICE ACTION

U.S. Serial No.: 10/712,419

Filed: November 12, 2003

Page 7 of 9

As stated above, in the present application, the portion of the device containing bound analyte is separated from the device without detachment from the immobilized binding partner. Therefore, applicants assert that Mazar *et al.* fail to teach the claimed device, kit or method. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §102(b).

Claim rejections under 35 U.S.C. §102(e)

The Examiner rejected Claims 1-4 and 7-10 under 35 U.S.C. § 102(e) as being anticipated by *LaBorde* (U.S. Patent No. 6,607,922). The Examiner states that *LaBorde* discloses an immunochromatographic assay using superparamagnetic beads or particles coupled with antibodies to capture analyte in a sample. The particles are disposed on a **test strip** that can be removed from a support member for archival or analysis by appropriate means. The Examiner concludes that even though *LaBorde* does not specifically teach a test kit comprising such a device, *LaBorde* anticipates the claims of the present application because it is nothing more than the device itself with no additional components. Applicants respectfully traverse the rejection.

LaBorde teaches an immunochromatographic assay method that relates broadly to lateral flow devices employing superparamagnetic particles as labels for the analyte to be detected. The bound complexes are captured in a predetermined area of the porous analytical membrane termed the “**capture region**” or “**capture zone**” (see column 3, line 1; and element 14 of the drawings). The lateral flow device of *LaBorde* contains: an assay support member (element 11 of drawings); a sample receiving element (element 17 of drawings); an immunoassay test strip containing a porous analytical membrane (element 13 of the drawings); at least one **capture region** (element 14 of the drawings); a backing member (element 12 of drawings); and a protective member (element 15 of drawings) with at least one magnetic standard line printed on the protective membrane (element 16 of the drawings). The Examiner states that *LaBorde* anticipates the claimed device because the test strip is removable.

FIRST AMENDMENT AND RESPONSE TO OFFICE ACTION

U.S. Serial No.: 10/712,419

Filed: November 12, 2003

Page 8 of 9

Applicants respectfully submit that, upon review of *LaBorde*, it can be clearly seen and understood from the text (see Figure 5: test strip removal), that removal of the “test strip” requires pealing the **entire** test strip from the housing, not separating only a portion of the test strip from the rest of the test strip as claimed in the present application. The amended claims of the present application specify that the portion of the device **containing the bound analyte** (i.e. corresponding to element 14 of *LaBorde*) is separated from the device, and the separated portion is then analyzed to provide information regarding the suspected analyte.

In addition, an essential feature of the device described by *LaBorde* is the presence of a **protective membrane** (element 15 of the drawings) covering the analytical membrane on the side opposite to the support member (see claim 1). Applicants respectfully submit that a protective membrane such as this would discourage one skilled in the art from separating the portion containing bound analyte from the test strip as claimed in the present application.

Applicants assert that *LaBorde* fails to teach the claimed device, kit or method. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §102(e).

Conclusion

Based upon the amendments and remarks provided above, Applicants believe that Claims 1-13 are in condition for allowance. A Notice of Allowance is therefore respectfully solicited. No additional fees are believed due; however, the Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment, to Deposit Account No. 11-0855. If the Examiner believes any informalities remain in the application that may be corrected by Examiner's Amendment, or there are any other issues

FIRST AMENDMENT AND RESPONSE TO OFFICE ACTION

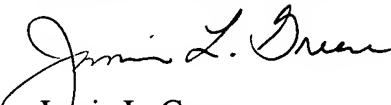
U.S. Serial No.: 10/712,419

Filed: November 12, 2003

Page 9 of 9

that can be resolved by telephone interview, a telephone call to the undersigned attorney at (404) 815-6500 is respectfully solicited.

Respectfully submitted,


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